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MEASUREMENT OF MECHANICAL PROPERTIES OF STENTS

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Abstract – The stents are the medical instruments used in invasive radiology for miniinvasive treatment of stenosis and aneurisms especially in the blood circulation system. Paper describes application of computer controlled device which was specially developed for measurement of mechanical properties of stents and vessels. This device together with the LabView programme enables automatic measurement of strain–stress curves of stents or vessels and in connection with the peristaltic pump can be used for the simulation of behaviour of stent inside the vessel system. All measurements are designed as a contactless and on-line so that the interaction of the measured sample with the probes and the mistakes due to insufficient synchronization of measurements are eliminated.

Keywords: stent, stress-strain curve

1. INTRODUCTION

The miniinvasive methods of stents or stentgrafts introduction for various indications is a very quickly developed trend in medicine but it is also very sophisticated as to the instrumentation. These methods of so called invasive radiology are used for correction of aneurysms or stenosis in the cardiovascular system, for correction of limited passage in the digestive system, in the urinary tract or in the biliary duct. The minimal traumatization of the patient, shorten the time, which the patient must spent in the hospital and with it related decrease of the cost of treatment are typical advantages of these methods. But also some disadvantages can occur, typically the leakage or the shift of stent (see proceedings of worldwide conferences [1], [2], [3]). The construction of the stent is the most often cause of these problems. The mechanical properties, dimension and the dynamical properties of the stent do not correspond to the properties of the vessel or generally of tissue where this stent is introduced. That is the reason, why we want to identify and to describe these relations between the mechanical properties of stents and tissues. Our originally developed device for measurement of mechanical properties of stents or vessels and results of measurements of nitinol and steel stents and short comparison of their chemical resistance are described in this paper. These measurements together with the modelling and simulation enable to design the parameters of the stent to fit the patient, which exactly correspond with the biomechanical properties of tissue in which it will be introduced.

2. CHEMICAL RESISTANCE

The stents are designed for the long time implantation so that the chemical interaction with the inner environment of the human body is expected. This interaction is substituted by experiments that simulate the expected corrosion in the real time. The electro chemical degradation tests (according to ISO/DIS 10993-15/2000) were applied for the evaluation of the resistance of Nitinol and steel wires, the typical material for the construction of stents. The special solution of electrolytes simulates the inner environment of the body, in our case the blood plasma+oxygen, but also the artificial saliva can be used. The level of corrosion of different material is given in the figures 1, 2, and 3.

Figure 1. Nitinol wire (radius 0.2 mm, exp. 160 min., magnification 205 x) in the artificial plasma.

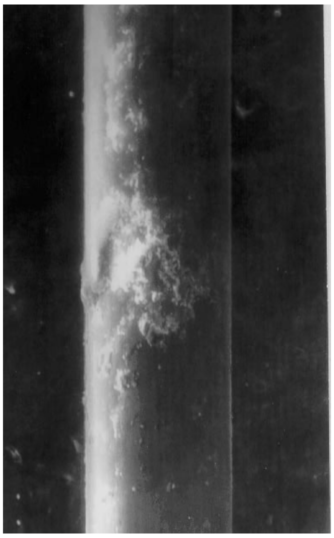

Figure 2. Steel 316V wire (radius 0.18 mm, exp.160 min, magnification 225 x) in the artificial plasma.

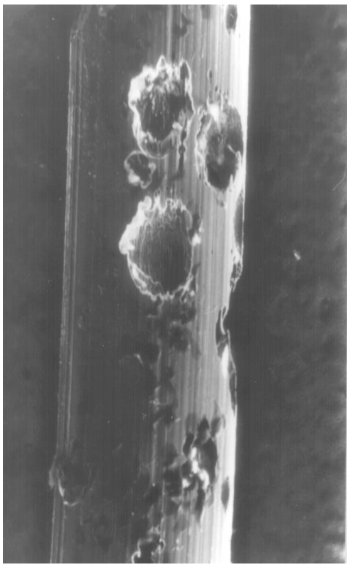

Figure 3. Steel AKV-EXTRA-S wire (radius 0.32 mm, exp. 160 min, magnification 145 x) in the artificial plasma.

There are many parameters that characterize the chemical resistance of material but the pictures are the most illustrative for the first information. Results show the different corrosion of tested materials that depends not only on the chemical composition, the surface protection but also on the technology of processing that can be different according to the producer.

3. MEASURING SYSTEM

The developed original measuring system enables measurement of mechanical properties of stents, measurement of strain-stress curves or simulation of interaction of the stent and vessel for exactly defined hemodynamic conditions, that are simulated by computer controlled peristaltic pump. Device consists of hermetically closed plastic glass vessel in which the stent is placed in the distilled water and joined into the system of tubes. The temperature of the water can be hold on constant value or its course can by defined by using the accurate digital thermostat with cooling that enables fast response. The tubes can be closed or opened by the valves so that the defined pressure affects the wall of stent. Pressure course and corresponding change of stent radius are on-line measured by the probes connected to the computer. All measurements are controlled and processed by the Labview programme. The original contactless method of measurement of the stent radius is based on the on-line processing of the digitalized image from the video camera (Topica TP 606D/3) by using the NI programme. The result radius of stent is calculated from the several planes in the predefined window of the stent digital image. The schematic diagram of the measuring system is given in the figure 4.

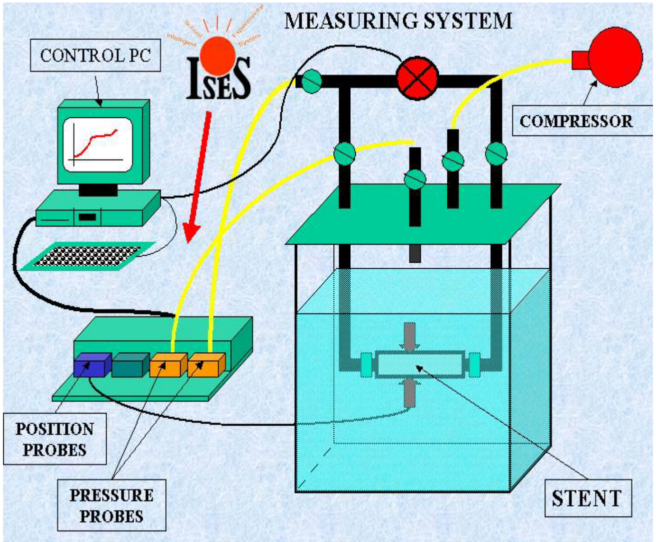

Figure 4. Diagram of measuring system

4. MECHANICAL PROPERTIES OF STENT

The mechanical properties of stents can be investigated in two ways. The first, theoretical way is that the mechanical properties are derived from the construction and used material of the stent. Second, experimental way supposes the direct measurement of mechanical properties of designed stents. It seems that the combination of these two accesses results in finding the adequate mechanical model of the stent that can be used for its design and for the simulation of its interaction with the biological system. We measured and compared the mechanical properties of two self expandable Nitinol and stainless steel stents. Both stents were of the same size (length 70 mm, thickness of the wall 0,2 mm and diameter 8 mm). Each stent was placed to the special holder into the measuring vessel containing the water. The holder doesn't limit the motion of the stent. This condition is very important because these types of stents have due to construction relatively high Poisson ratio (ratio between the change of radius and change of length). The pressure inside respectively outside of the stent was gradually increased and decreased and the corresponding mechanical deformation (change of the radius) of the stent was continuously measured. The pressure changes were chosen in the range, which could be expected in the circulation system of the human body not only under the normal but also under the extreme conditions.

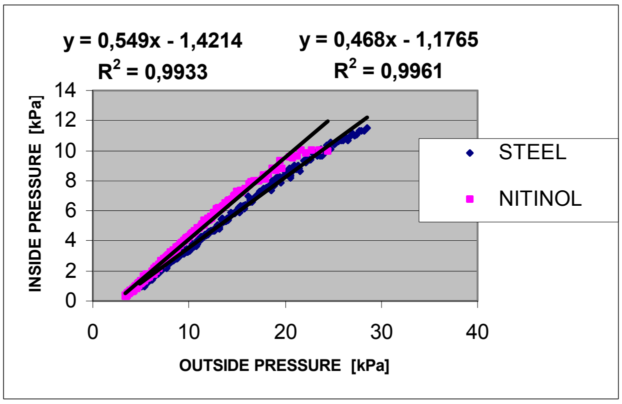

Figure 5. Relation between pressures inside and outside the steel and Nitinol stent.

Figure 5 expresses the response of the pressure inside the stent on the pressure changes outside the stent. We can notice that in the range of the normal pressures (it means blood pressure) the relation is nearly linear and the slope of the linear regression line corresponds to the rigidity of the stent. The slope of the graph can reach values in the range from zero to one. Zero value corresponds to the situation when the stent doesn't change its radius according to the pressure changes, it means that it is totally rigid. In the opposite case when the stent is ideally soft, it means that it follows without resistance the pressure changes, the slope is equal to one. There is the same pressure inside and outside the stent in this case. We can derive conclusion that the rigidity of stent is higher when the slope of graph is smaller. It implies from the graph that the steel stent is more rigid in comparison with the nitinol one. The tube is the typical shape of stent and we can derive the Hooks law for the tube in the form:

$$T = E * d * (r - r_0)/r_0$$

where T [N/m] is the tension, d [m] is the thickness of the wall of the stent, r [m] and r_0 [m] are the radius after compression respectively radius without compression. If we display relation between the relative change of radius that corresponds to the pressure on the wall of stent we get for the Nitinol stent the graph in the Figure 6. The slope of the regression line corresponds according to the above equation to the product of Young modulus E [Pa] and thickness d. The parameter d is given, so that E can be calculated and it is equal to 887,9 kPa.

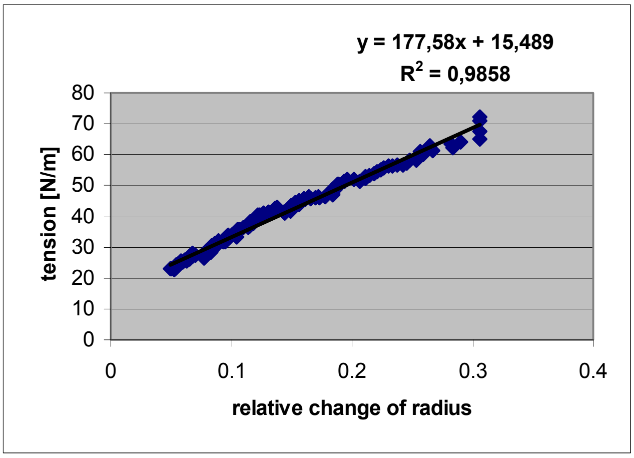

Figure 6. Strain-stress curve for the Nitinol stent.

4. CONCLUSION

The mechanical properties and on the opposite side the chemical resistance of materials used for long time implants cannot tune for each application and it is necessary choice the compromise. It is strictly recommended to simulate the expected interactions by using the models of stents and corresponding tissues, where the stent is typically applied. The results of measurement are necessary for design and identification of the parameters of the models.

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